



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,198	08/10/2001	James Arthur Hoffmann	X12383N	6700
25885	7590	07/12/2004	EXAMINER	
ELI LILLY AND COMPANY			DEBERRY, REGINA M	
PATENT DIVISION				
P.O. BOX 6288			ART UNIT	
INDIANAPOLIS, IN 46206-6288			PAPER NUMBER	
			1647	

DATE MAILED: 07/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/928,198

Applicant(s)

HOFFMANN ET AL.

Examiner

Regina M. DeBerry

Art Unit

1647

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 5/18/04 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 18 June 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 128.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

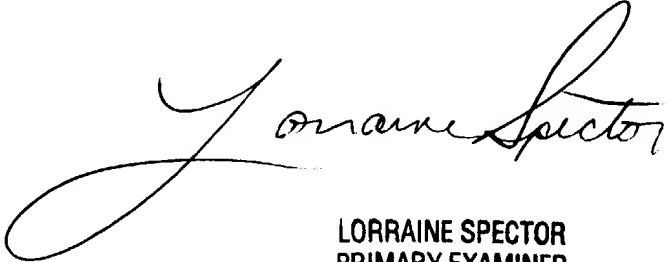
8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5/25/04.
10. ☒ Other: See Continuation Sheet

Continuation of 2. NOTE: If the amendment was entered, newly submitted claims 129-131 would be rejected under 35 USC 112, First Paragraph, Written Description (New Matter). Claim 130 recites, "the pharmaceutically acceptable, solution formulation of claim 128, wherein the solution is contained in a sealed vial". Applicant states that support for the new claim 130 can be found, inter alia, on page 17 lines 31-33 in the definition of a vial. Applicant states that retaining the solution in a sterile state indicates that the vial is sealed. This is not found persuasive. The specification as originally filed does not provide support for this new limitation. The instant claim now recites a limitation which was not disclosed in the specification as originally filed, and now changes the scope of the instant disclosure as filed.

Newly submitted claims 129 and 131 recite, "the pharmaceutically acceptable solution formulation of claim 128, wherein the solution is suitable for administration without being reconstituted by the patient" and "the pharmaceutically acceptable, solution formulation of claim 128, wherein the solution is prepared by reconstitution by the patient", respectively. Applicant directs support to page 38, lines 23-30. The instant specification does not teach that the solution is reconstituted. The instant specification teaches that lyophilized FSH (or FSH variant) is lyophilized. The newly submitted claims read on the solution being reconstituted (or not) instead of lyophilized FSH. The newly submitted claims now recite limitations which were not disclosed in the specification as originally filed, and now change the scope of the instant disclosure as filed.

If the amendment was entered newly submitted claims 129 and 131 would be rejected under 35 USC 112, Second Paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicant regards as the invention. The limitations, "wherein the solution is prepared by reconstitution by the patient" and "wherein the solution is suitable for administration without being reconstituted by the patient" is vague and indefinite because it is not clear if the solution is prepared by someone other than the patient (i.e. nurse or doctor).

Continuation of 10. Other: Applicant failed to address the maintained provisional rejection of claim 128 under the judicially created doctrine of double patenting over claims 159 and 160 of copending Application No. 09/744,431 in view of Keene et al., Skrabanja and Andya et al.



LORRAINE SPECTOR  
PRIMARY EXAMINER